

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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U.S. DISTRICT COURT
DISTRICT OF MASSACHUSETTS
SOUTHERN DISTRICT
JAN 13 2005

IN RE VASO ACTIVE PHARMACEUTICALS)
SECURITIES LITIGATION)
This Document Relates To:) Master Docket No. 04-10708-RCL
ALL ACTIONS)

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Lead Plaintiffs Edwin Choi, Richard Ching and Joe Huback ("Lead Plaintiffs") and plaintiff Richard A. Ruterman (together with Lead Plaintiffs, "Plaintiffs"), individually and on behalf of all other persons similarly situated, allege the following upon personal knowledge as to themselves and their purchases of the Class A common stock of Vaso Active Pharmaceuticals, Inc. ("Vaso" or the "Company"), and upon information and belief based upon the investigation of their attorneys as to all other matters. This investigation included, among other things, a review and analysis of the public filings by Vaso with the United States Securities and Exchange Commission ("SEC"), press releases and other public statements published by and regarding Vaso, a transcript of an interview with Vaso's President, Chief Executive Officer ("CEO"), and Chairman, John J. Masiz ("Masiz"), and reports by news services about Vaso. Counsel for Plaintiffs has also thoroughly reviewed the complaint in the settled civil injunction action filed by the SEC against Vaso and Masiz on August 17, 2004. Plaintiffs believe that the ongoing investigations of their counsel will yield further information in support of the claims alleged herein. Based upon the substantial facts already uncovered, and alleged herein, Plaintiffs also believe that substantial additional evidentiary support will exist for the allegations set forth herein

after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action brought under Sections 11 and 15 of the Securities Act of 1933 (the “Securities Act”), 15 U.S.C. §§ 77k and 77o, Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder by the SEC, including Rule 10b-5, 17 C.F.R. § 240.10b-5. The claims under the Exchange Act are brought on behalf of all persons and entities who purchased or otherwise acquired Vaso Class A common stock on the open market between December 9, 2003 and March 31, 2004, inclusive (the “Class Period”). The claims under the Securities Act are brought on behalf of all persons and entities who acquired shares of Vaso’s Class A common stock in connection with the Company’s initial public offering on or about December 9, 2003 (the “IPO”) pursuant, or traceable, to Vaso’s Form SB-2 registration statement filed on July 7, 2003 and its Forms SB-2/A amended registration statements filed on September 12, 2003, October 16, 2003, November 13, 2003, and December 9, 2003 (collectively the “Registration Statement”).

2. According to the Company, Vaso was an early stage company focused on the commercialization, marketing, and sale of over-the-counter (OTC) drug products that incorporated a patented transdermal (i.e., through the skin) drug delivery technology, which was exclusively licensed to Vaso by its parent company, BioChemics, Inc. (“BioChemics”). This transdermal technology, referred to in the Company’s SEC filings as vaso active lipid encapsulated, or VALE, transdermal delivery technology, purportedly provided “a highly efficient, reliable and targeted method of drug delivery” into

the bloodstream “that does not require the use of a needle or patch and eliminates many of the common side effects of pills, such as bleeding and ulcers.”

3. Defendants (defined below) represented in the Registration Statement that Vaso had begun marketing and was preparing for the commercial launch of three OTC, transdermal drug products – Athlete’s Relief, Osteon, and deFEET (later renamed Termin8) (collectively the “Current Products”) – two of which, deFEET and Athlete’s Relief, purportedly employed the Company’s exclusive VALE transdermal drug delivery technology. The Registration Statement also represented that Vaso’s Current Products “have been through the research and development, pre-clinical study and clinical trial stages and have received FDA approval.”

4. Based on these representations, Defendants conducted the IPO at an offering price of \$5.00 per share and raised over \$8.3 million in gross proceeds and approximately \$6.4 million in net proceeds. During the Class Period, the Company was also able to raise an additional \$7.5 million in a private placement of its securities and pay for marketing and advertising services with warrants to purchase Vaso common stock.

5. Throughout the Class Period, Vaso continued to represent that Vaso’s Current Products were compliant with FDA rules and regulations and were ready for commercial launch.

6. However, unbeknown to the investing public, Vaso’s claims regarding its Current Products were materially false and misleading. Vaso had not, and has not, received any approval from the FDA for the marketing or sale of any of its OTC drug products. Moreover, because the Current Products were represented to employ a new mode of drug administration, i.e., transdermal, that had

not been considered by the FDA as “generally recognized as safe and effective, or GRASE,” these products were not eligible for participation in the FDA’s OTC Review Program. As a result, Vaso was required to obtain pre-market approval from the FDA in the form of an approved new drug application (NDA) or abbreviated new drug application (ANDA) before it could market or sell its Current Products.

7. The perpetuation of these material false and misleading statements was brought to an end by the SEC who suspended trading in the Company’s stock effective at 9:30 AM on April 1, 2004. According to the Company, the SEC imposed the trading suspension because of questions regarding the accuracy of assertions by the Company and by others, in press releases, its annual report, its Registration Statement and public statements to investors concerning, among other things: (1) the FDA approval of certain key products, and (2) the regulatory consequences of the future application of their primary product. After the initiation of the trading suspension, Vaso ceased the marketing and sale of its Current Products and has to date not resumed the marketing and sale of these products.

8. On April 2, 2004, the Nasdaq Stock Market, Inc. (“Nasdaq”) notified Vaso that it had commenced an inquiry concerning the Company’s compliance with Nasdaq inclusion requirements. In response, the Company chose to voluntarily cause its shares to be removed from Nasdaq, and the Company’s securities were delisted from the Nasdaq effective April 8, 2004.

9. On August 17, 2004, the SEC, who consulted the FDA with respect to Vaso, filed a complaint against the Company and Masiz, alleging that these defendants made material misrepresentations and omissions in both public statements and filings made with the SEC by falsely

claiming, among other things, that Vaso's Current Products had received FDA approval (the "SEC Complaint").

10. After the Class Period, the Company and Masiz settled with the SEC and restated the Company's Form 10-KSB for the year ended December 31, 2003 to correct various false and misleading statements concerning the Current Products. As part of his settlement with the SEC, Masiz was fined \$80,000 and agreed to be barred from acting as an officer or director of any public company, including Vaso, for five years.

11. In its restated Form 10-KSB, Vaso no longer described its Current Products as having a transdermal effect, instead describing each as having only a topical formulation and effect. Moreover, the Company disclosed that because the VALE transdermal technology required NDA approval by the FDA, the Company would not pursue the development of this technology until it had "secured a partnership with a larger marketing partner." Thus, Vaso effectively abandoned the very technology which it had described during the Class Period as the sole focus of the Company's business strategy and activities.

12. On March 31, 2004, the last day of the Class Period, the Company's Class A common stock closed at a price of \$7.59 per share. After the SEC trading suspension expired, trading in the Company's stock resumed on the over-the-counter (OTC) Bulletin Board on April 16, 2004. On that date, the Company's stock closed at a price \$1.75 per share, according to the Pink Sheets, representing a 77% decline from its closing price on March 31, 2004. The Company's Class A common stock, which had a closing price as high as \$13.10 per share during the Class Period, now

trades on the OTC Bulletin Board for less than a \$0.50 per share.¹

13. Due to Defendants' dissemination of materially false and misleading statements throughout the Class Period concerning Vaso's Current Products and the Company's ability to pursue commercialization of OTC drug products that employed the VALE transdermal drug delivery technology, the price of Vaso's Class A common stock was artificially inflated in price at all relevant times, and purchasers of the Company's common stock, including Plaintiffs, were damaged as a result.

JURISDICTION AND VENUE

14. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act as (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5), and Sections 11 and 15 of the Securities Act (15 U.S.C. §§77k and 77o).

15. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. §78aa), Section 22 of the Securities Act (15 U.S.C. §77v), and 28 U.S.C. §§1331 and 1337.

16. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). Vaso maintains its principal executive offices in this District, and many of the acts complained of, including the dissemination to the investing public of materially false and misleading information, occurred within this District.

17. In connection with the acts, conduct, and wrongs complained of herein, Defendants,

¹Except where noted herein, all share numbers, per share stock prices, and option exercise prices contained herein reflect the Company's 3 for 1 stock split effective March 5, 2004.

directly or indirectly, used the means and instrumentalities of interstate commerce.

THE PARTIES

18. Lead Plaintiffs purchased Vaso Class A common stock during the Class Period, as set forth in their certifications previously filed with the Court and incorporated by reference, and have suffered damages as a result.

19. Plaintiff Richard A. Ruterman purchased shares of Vaso Class A common stock during the Class Period, as set forth in his certification of named plaintiff, which is annexed hereto as Exhibit A, and has suffered damages as a result.

20. Defendant Vaso is a Delaware corporation with its headquarters and executive offices located in Danvers, Massachusetts. During the Class Period, shares of Vaso common stock traded on the Nasdaq under the ticker symbol "VAPH." As of March 18, 2004, there were over 5,798,604 shares of Vaso Class A common stock outstanding.

21. Defendant Masiz was, at all relevant times, Vaso's President, CEO, and Chairman, and the President, CEO, and Chairman of BioChemics, Vaso's parent Company and principal stockholder. At all relevant times, BioChemics owned 4,500,000 shares of Vaso's Class B common stock, representing approximately 70% of the combined voting power of the outstanding common stock of the Company. At all relevant times, Masiz had over 85% of the sole beneficial ownership of BioChemics. As a result, as stated in the Company's Form 10-KSB for the year ended December 31, 2003, Masiz controls both BioChemics and Vaso. Defendant Masiz signed the Registration Statement and the Company's Form 10-KSB for the year ended December 31, 2003, which contained materially false

and misleading statements, as detailed herein.

22. Defendant Stephen G. Carter, PH.D was, at all relevant times since June 2003, Vaso's Chief Scientific Officer ("CSO") and director. At all relevant times from 1999, defendant Carter also served as CSO and as a director of BioChemics. Defendant Carter signed the Registration Statement and the Company's Form 10-KSB for the year ended December 31, 2003, which contained materially false and misleading statements, as detailed herein.

23. Defendant Joseph Frattaroli was, at all relevant times, Vaso's Chief Financial Officer and Secretary. Defendant Frattaroli signed the Registration Statement, which contained materially false and misleading statements, as detailed herein.

24. Defendant Bruce A. Shear was, at all relevant times, a director of Vaso. Defendant Shear signed the Registration Statement, which contained materially false and misleading statements, as detailed herein.

25. Defendant Gary Fromm, PH.D was, at all relevant times, a director of Vaso. Defendant Fromm signed the Registration Statement, which contained materially false and misleading statements, as detailed herein.

26. Defendant Brian J. Strasnick, PH.D was, at all relevant times, a director of Vaso. Defendant Strasnick signed the Registration Statement, which contained materially false and misleading statements, as detailed herein.

27. Defendant William P. Adams, M.D was, at all relevant times, a director of Vaso. Defendant Adams signed the Registration Statement, which contained materially false and misleading

statements, as detailed herein.

28. Defendant Robert E. Anderson was, at all relevant times, a director of Vaso. Defendant Anderson signed the Registration Statement, which contained materially false and misleading statements, as detailed herein.

29. Defendants Shear, Fromm, Strasnick, Adams, and Andersen are referred to herein as the Outside Director Defendants.

30. Defendants Vaso, Masiz, Carter, Frattaroli, Shear, Fromm, Strasnick, Adams, Andersen, and Kashner (defined below) are collectively referred to herein as Defendants.

31. Defendants Masiz, Carter, and Frattaroli's and the Outside Directors' signatures on the Registration Statement make them primarily liable under Section 11 of the Securities Act for the materially false and misleading statements that appeared in that Registration Statement.

32. As officers and controlling persons of a publicly-held company whose common stock was registered with the SEC pursuant to the Exchange Act, and was traded on the Nasdaq, and governed by the provisions of the federal securities laws, defendants Masiz and Carter had a duty to disseminate promptly, accurate and truthful information with respect to the Company's financial condition and operations, so that the market price of the Company's publicly-traded common stock would be based upon truthful and accurate information. Defendants Masiz and Carter's material misrepresentations during the Class Period violated these specific requirements and obligations.

33. Because of their positions of control and authority as an officers and directors of the Company, defendants Masiz and Carter were able to and did control the content of the Company's

filings with the SEC. Defendants Masiz and Carter were provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Moreover, defendants Masiz and Carter by virtue of their directorships and executive and managerial positions with Vaso and BioChemics, directly participated in the management of the Company and BioChemics, were directly involved in the day-to-day operations of the Company and BioChemics at the highest level, and were privy to confidential proprietary information concerning the Company, its business and operations, clinical trials, and its compliance and non-compliance with FDA regulations.

34. Defendants Vaso, Masiz and Carter are primary liable as participants in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Vaso common stock, by disseminating materially false and misleading statements and concealing material adverse facts. The scheme deceived the investing public regarding Vaso's business, strategies, prospects, financial condition, and the intrinsic value of Vaso common stock and caused Plaintiffs and other members of the Class to purchase Vaso common stock at artificially inflated prices. Because of defendants Masiz and Carter's positions with the Company and BioChemics, they had access to the undisclosed adverse information about the Company's principal technology, clinical trials, compliance and non-compliance with FDA regulations, and its business prospects via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof, and via reports and other information provided to them in connection therewith.

35. Defendant Kashner Davidson Securities Corp. (“Kashner”) is a brokerage and investment banking firm with its principal office located in Sarasota, Florida. Kashner was the lead underwriter for the IPO. Kashner substantially participated in the commission of the wrongs alleged herein and received substantial fees in connection with the IPO. In connection with the IPO, Kashner was to receive approximately \$475,000 in underwriting fees plus five year warrants, at a price of \$0.001 per warrant, to purchase 435,000 shares of Vaso Class A common stock at an exercise price of \$2.58 per share. The warrants were exercisable during the four year period commencing one year from approximately December 9, 2003.

36. Prior to the IPO, defendant Kashner was required to, and did, conduct an investigation into the business, operations, prospects, financial condition and accounting and management control systems of Vaso, known as a “due diligence investigation.” In the course of such investigation, Kashner would have obtained knowledge of the facts alleged herein if it acted with reasonable care. Specifically, had Kashner completed the most cursory of investigations, it would have discovered that neither Vaso nor BioChemics had sought nor received FDA approval for Vaso’s Current Products and that the representation in the Registration Statement that the Current Products had received FDA approval was patently false. Kashner caused the materially false and misleading Registration Statement to be delivered to potential and actual purchasers of Vaso common stock in connection with offers and sales thereof. At all relevant times, Kashner had a duty to promptly disseminate truthful and accurate information with respect to Vaso and its affairs.

SUBSTANTIVE ALLEGATIONS

BACKGROUND

37. According to the Company, Vaso began its operations in January 2001 as a division of BioChemics, a biopharmaceutical company focused on the development of transdermal drug delivery systems. According to the Company, Vaso's business focus was the commercialization of a broad range of products incorporating BioChemics's patented VALE transdermal drug delivery technology, which was exclusively licensed to Vaso by BioChemics for use in the OTC pharmaceutical market.

38. In the Registration Statement, the Company's "VALE system" was described as "a patchless, lipid-based delivery system, which uses an active, as opposed to a passive, process to deliver drugs into the bloodstream." In the Registration Statement, Vaso also touted the Company's VALE technology as providing an "efficient, predictable and reliable transdermal drug delivery system that eliminates the need for a patch and allows for the efficient and effective delivery [of] a myriad of drugs that can not be effectively delivered transdermally using prior transdermal drug delivery technology."

SECURITIES ACT CLAIMS

39. The claims brought under the Securities Act are separate and distinct from Counts III and IV asserted herein under the Exchange Act. The allegations supporting the Securities Act claims brought herein do not require the pleading of, and do not plead, fraudulent intent or scienter and are therefore, not subject to the pleading requirements of the Private Securities Litigation Reform Act of 1995 and Rule 9(b) of the Federal Rules of Civil Procedure. The Section 11 claim under the Securities

Act is brought against all Defendants on behalf of all acquirers of Vaso Class A common stock pursuant, or traceable, to the Registration Statement in connection with the IPO. This claim alleges only that the Registration Statement contained materially false and misleading statements concerning Vaso's Current Products.

40. Pursuant to the Registration Statement, Vaso completed its IPO of 1,450,000 shares of Class A common stock, plus an over-allotment of 217,500 shares, at a pre-stock split price of \$5.00 per share, raising over \$8.3 million in gross proceeds and approximately \$6.4 million in net proceeds for the Company.

41. The Registration Statement was signed by defendants Masiz, Carter, and Frattaroli and each of the Outside Directors.

False and Misleading Statements in the Registration Statement

42. The Registration Statement contained the following materially false and misleading statements: (1) that the Company's Current Products – deFEET (renamed Termin8 after the IPO), Athlete's Relief, and Osteon – “have been through the research and development, pre-clinical study and clinical trial stages and have received FDA approval”; (2) that the Current Products each had a transdermal effect, i.e., that deFEET was a “topically applied, transdermal athlete's foot anti-fungal medication,” that Athlete's Relief was a “topically applied, transdermal muscle and joint pain treatment,” and that Osteon was a “topically applied, transdermal arthritis pain reliever”; and (3) that deFEET and Athlete's Relief employed the Company's VALE drug delivery system.

43. The statements in the preceding paragraph were materially false and misleading when

made. First, neither Vaso nor BioChemics had received FDA approval for any of the Current Products, as revealed after the Class Period by the SEC Complaint and the Company's post-Class Period disclosures. Moreover, in the Registration Statement, Vaso failed to disclose the FDA regulations concerning the marketing of OTC drugs and the regulatory procedures pursuant to which Vaso or BioChemics had purportedly received "FDA approval" for the Current Products. The Registration Statement also failed to disclose that Vaso products that were represented as incorporating the Company's VALE technology could not be sold without FDA approval. Second, in the Company's amended Form 10-KSB for the year ended December 31, 2003, filed after the Class Period on July 21, 2004 ("10-KSB/A"), the Company revealed for the first time that none of the Current Products had a transdermal effect and none employed the VALE transdermal drug delivery technology, contrary to the representations concerning these products in the Registration Statement. Specifically, the 10-KSB/A stated for the first time that the Current Products used the Company's "PENtoCORE topical formulation," which, unlike VALE, was not covered by any patents and had only a topical effect, rather than the purported transdermal effect of VALE. In the Company's Registration Statement, PENtoCORE was described only as a registered trademark of BioChemics licensed to Vaso, not as a drug formulation distinct from VALE. There was no other mention of PENtoCORE included in the Registration Statement.

44. In addition, the Registration Statement including the following materially false and misleading statements concerning the clinical testing of the Company's deFEET product:

In a pilot clinical trial, *supervised by independent physicians and analyzed by the New England Medical Center in Boston, MA*, 20 severely infected athlete's foot

patients were treated and studied over a 42-day period. There were two groups in the study, one treated with deFEET and the other with Schering-Plough's Tinactin®. In this study, deFEET eliminated the infection in 90% of the test group in 7 days and 100% of its patient population in 10 days. Tinactin®, which also uses Tolnaftate in the same concentration as deFEET, required 42 days to cure its first patient. These results demonstrate the ability of the VALE technology to deliver Tolnaftate much more effectively than a product not utilizing VALE technology. (Emphasis added)

45. In truth, as revealed by a March 9, 2004 *Street.com* article and a March 9, 2004 press release issued by the Company in response to that article, the “pilot clinical trial” was conducted by only one physician hand-picked by BioChemics and was not “supervised by independent physicians.” Moreover, the New England Medical Center’s involvement in the clinical trial was limited at best. The medical center was hired by BioChemics to analyze the statistical data compiled by BioChemics, something the center does routinely for paying customers. Robin Ruthazer, the center employee who analyzed BioChemics’s statistics, stated to the *Street.com* that she couldn’t draw any conclusions about the effectiveness of the product, since she had no hand in selecting the patients and gathering the evidence. The Registration Statement also failed to disclose that the clinical trial was conducted in 1998, approximately 6 years before the IPO.

EXCHANGE ACT CLAIMS

Vaso’s False and Misleading Statements During the Class Period

46. In addition, to the materially false and misleading statements contained in the Registration Statement, as set forth above, defendants Vaso, Masiz, and Carter made several additional materially false and misleading statements, as set forth below.

47. On March 26, 2004, Vaso filed its annual report on Form 10-KSB for the year ended

December 31, 2003 (“10-KSB”), which was signed by defendants Masiz and Carter, among others. In the 10-KSB, Vaso again represented that the Company was focused “on commercializing, marketing and selling over-the-counter, or OTC, pharmaceutical products that incorporate the vaso active lipid encapsulated, or ‘VALE’, transdermal drug delivery technology.” The 10-KSB also stated: “We will market the VALE technology under the PENtoCORE trademark.”

48. The 10-KSB included the following materially false and misleading statements: (1) that each of the Company’s Current Products – Termin8, Athlete’s Relief, and Osteon – “has been through the research and development stage and are qualified under FDA OTC monographs and have been registered as such”; (2) that the Current Products each had a transdermal effect, i.e., that Termin8 was a “topically applied, transdermal anti-fungal medication,” that Athlete’s Relief was a “topically applied, transdermal muscle and joint pain treatment,” and that Osteon was a “topically applied, transdermal arthritis pain reliver”; and (3) that Termin8 employed the Company’s VALE transdermal drug delivery system.

49. The statements in the paragraph above were materially false and misleading when made. First, none of the Current Products, to the extent they were represented as employing a transdermal drug delivery system, satisfied the FDA OTC monograph requirements, as revealed after the Class Period by the SEC Complaint and the Company’s post-Class Period disclosures. Specifically, VALE was a new delivery system that was not covered under the FDA’s OTC Review Program, and therefore, drugs employing VALE could not be marketed in conformity with an existing OTC drug monograph and required pre-market approval by the FDA. Moreover, Vaso (1) failed to